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(54) **Title:** IMPEDANCE MEASUREMENT FOR AN IMPLANTABLE DEVICE

(57) **Abstract:** A method and an apparatus for determining an impedance experienced by a lead associated with the implantable
device. A substantially constant current signal is provided through a first terminal and a second terminal of the lead. A voltage
across the first and second terminals is measured. An impedance across the first and second terminals is determined based upon the
constant current signal and the measured voltage.

IMPEDANCE MEASUREMENT FOR AN
IMPLANTABLE DEVICE

BACKGROUND OF THE INVENTION
1. FIELD OF THE INVENTION

This invention relates generally to implantable medical devices, and more

particularly to methods, apparatus, and systems for monitoring power consumption

and impedance characteristics relating to implantable medical devices.

2. DESCRIPTION OF THE RELATED ART

There have been many improvements over the last several decades in medical

treatments for disorders of the nervous system, such as epilepsy and other motor

disorders, and abnormal neural discharge disorders. One of the more recently

available treatments involves the application of an electrical signal to reduce various

symptoms or effects caused by such neural disorders. For example, electrical signals

have been successfully applied at strategic locations in the human body to provide

various benefits, including reducing occurrences of seizures and/or improving or

ameliorating other conditions. A particular example of such a treatment regimen

involves applying an electrical signal to the vagus nerve of the human body to reduce

or eliminate epileptic seizures, as described in U.S. Patent No. 4,702,254 to Dr. Jacob

Zabara, which is hereby incorporated by reference in its entirety in this specification.

Electrical stimulation of the vagus nerve may be provided by implanting an electrical

device underneath the skin of a patient and performing a detection and electrical

stimulation process. Alternatively, the system may operate without a detection

system if the patient has been diagnosed with epilepsy, and may periodically apply a

series of electrical pulses to the vagus (or other cranial) nerve intermittently throughout the day, or over another predetermined time interval.

Many types of implantable medical devices, such as pacemakers and drug infusion pumps, typically include custom integrated circuits that are complex, expensive, and specific to the intended use. These systems also typically employ proprietary communications techniques to transfer information between the implant and an external programmer. The custom circuitry is developed because of the need to keep power consumption at a minimum, to conform to the allowable size for implantable devices, and to support the complexity of the detection and communication techniques, while still supplying the particular intended therapy.

Typically, implantable medical devices (IMDs) involving the delivery of electrical pulses to body tissues, such as pacemakers (heart tissue) and vagus nerve stimulators (nerve tissue), comprise a pulse generator for generating the electrical pulses and a lead assembly coupled at its proximal end to the pulse generator terminals and at its distal end to one or more electrodes in contact with the body tissue to be stimulated. One of the key components of such IMDs is the power supply, ordinarily a battery, which may or may not be rechargeable. In many cases surgery is required to replace an exhausted battery. To provide adequate warning of impending depletion of the battery and subsequent degradation of the operation of the EVID, various signals may be established and monitored. One such signal is an elective replacement indicator (ERI) that may indicate that an electrical device component, such as a battery, has reached a point where replacement or recharging is recommended. Another indicator may be an end of service (EOS) signal, which may

provide an indication that the operation of the implanted device is at, or near, termination and delivery of the intended therapy can no longer be guaranteed. ERI and EOS are commonly used indicators of the present status of an M D battery. ERI is intended to be a warning signal of an impending EOS indication, providing

5   sufficient time (e.g., several weeks or months) in typical applications to schedule and perform the replacement or recharging.

Generally, battery-powered IMDs base the EOS and the ERI signals on battery voltage and/or battery impedance measurements. One problem associated with these

10   methodologies is that, for many battery chemistries, these measured battery characteristics do not have monotonically-changing values with respect to remaining charge. For example, lithium/carbon monofluoride (Li/CFx) cells commonly used in neurostimulators and other IMDs have a relatively flat voltage discharge curve for the majority of their charge life, and present status of the battery cannot be accurately and

15   unambiguously determined from a measured battery characteristic.

Another problem associated with this methodology is the variability of current consumption for a specific device's programmed therapy or circuitry. This variability, combined with the uncertainty of the battery's present status prior to ERI

20   or EOS, hinders reliable estimation of the anticipated time until reaching ERI or EOS. For scheduling purposes, it is desirable to have a constantly available and reliable estimate over all therapeutic parameter ranges and operation settings of the time until the device will reach EOS, and provide an indication, similar in purpose to ERI, when that time reaches a specific value or range.

25

Impedance measurements are used to assess the integrity of the electrical leads that deliver the stimulation provided by a pulse generator. A change in the impedance across the leads that deliver the electrical pulses may be indicative either of changes in a patient's body or in the electrical leads themselves. For example, damage in the

5   lead, which may be induced by a break in one or more filaments in a multifilament lead wire, or changes in the body tissue where stimulation is delivered, may affect the efficacy of the stimulation therapy. Therefore, it is desirable for changes in the lead impedance, which may be indicative of various changes or malfunctions, to be accurately detected.

10

For instance, the integrity of the leads that deliver stimulation is of interest to insure that the proper therapy dosage is delivered to the patient. Some IMDs, most notably pacemakers, provide a voltage-controlled output that is delivered to one or more body locations (such as the heart). Other EViDs, such as a vagus nerve

15   stimulator device developed by Cyberonics, Inc., provide a current-controlled output. Generally, however, state-of-the-art measurements of lead impedance involve an analysis of the delivery of a voltage signal from a capacitive (C) energy storage component through the resistive (R) lead impedance and an examination of the decay of that signal based upon a time-constant proportional to the product of the resistance

20   and capacitance (RC). The total equivalent impedance present at the leads and the known energy source total equivalent capacitance cause a time-constant discharge curve. As the voltage on the capacitance is discharged through the resistance, the exponential decay of this voltage may be monitored to determine the decay time constant RC. From that time constant and an estimate of the known equivalent

25   capacitance C, the equivalent resistance R presented by the leads may be

mathematically estimated. However, this type of measurement may lead to inaccuracies for a number of reasons, including the fact that the discharging of the voltage signal may be affected by other resistances and capacitances in the system, the accuracy of the capacitor, the time, voltage, and algorithmic accuracies of the

5   measurement system, and the like. It would be desirable to have a more efficient and accurate method, apparatus, and/or system to measure or assess the impedance present at the leads that deliver an electrical stimulation or therapy.

The present invention is directed to overcoming, or at least reducing, the

10   effects of, one or more of the problems set forth above.

SUMMARY OF THE INVENTION

In one aspect of the present invention, a method is provided for projecting an end of service date and/or elective replacement indication of a power supply in an

15   implantable medical device, the power supply having an initial electrical charge and a final electrical charge. According to a preferred embodiment, the method comprises determining an active charge depletion of an IMD, determining an inactive charge depletion of the implantable device, and determining a time period until an end of service (EOS) and/or elective replacement indication (ERI) of a power supply

20   associated with the IMD based upon the active charge depletion, the inactive charge depletion, and the initial and final (EOS) battery charges.

In another embodiment, a method for projecting an end of service and/or an elective replacement indication of an IMD having a power supply with an initial

25   electrical charge and a final electrical charge comprises determining a current usage

rate for at least one future idle period, and determining charge depleted during at least one previous idle period. The method also comprises determining a current usage rate for at least one future stimulation period, and determining charge depleted during at least one previous stimulation period. A total charge depleted by the IMD is

5   determined based upon the charges depleted during the at least one previous idle period and the at least one previous stimulation period, respectively. A total future charge depletion is determined based upon the current usage rate during the at least one future stimulation period and the current usage rate during the at least one future idle period. A time period until an end of service (EOS) and/or ERI of a power

10   supply (e.g., a battery) of the IMD is determined based upon the total charge depleted and the total future charge depletion, as well as the initial and final (EOS) battery charges.

In a further embodiment of the present invention, a method is provided for

15   projecting an end of service date and/or elective replacement indication of a power supply in an implantable medical device, the power supply having an initial electrical charge and a final electrical charge. According to a preferred embodiment, the method comprises determining a charge depletion of an IMD and determining a time period until an end of service (EOS) and/or elective replacement indication (ERI) of a

20   power supply associated with the IMD based upon the charge depletion and the initial and final (EOS) battery charges.

hi a further embodiment of the present invention, a method for projecting an end of service and and/or elective replacement indication of an IMD having a power

25   supply with an initial electrical charge and a final electrical charge comprises

determining a previous active depleted charge of an IMD and determining a future or
potential active current usage rate of the IMD. The method also comprises
determining a previous inactive depleted charge of the IMD and determining a future
or potential inactive current usage rate of the IMD. A time period until an EOS
5   and/or ERI of a power supply associated with the implantable device is determined
based upon the previous active depleted charge, the potential active current usage rate,
the previous inactive depleted charge, the potential inactive current usage rate, and the
initial and final (EOS) battery charges.

10   In another aspect of the present invention, an implantable medical device is
provided for projecting an end of service and/or an elective replacement indication of
a power supply in the IMD. The IMD comprises a battery with an initial electrical
charge and a final electrical charge to provide power for at least one operation
performed by the implantable device. The device further comprises a stimulation unit
15   operatively coupled to the battery, the stimulation unit providing a stimulation signal
to at least one body location. The stimulation unit preferably comprises an electrical
pulse generator, but may alternatively comprise a drug pump, a magnetic field
generator, a mechanical vibrator element, or other device for stimulating body tissue.
The IMD also preferably comprises a controller operatively coupled to the stimulation
20   unit and the battery. The controller is adapted to determine an active current usage
rate and an inactive current usage rate of the IMD, as well as an active electrical
charge depleted by the battery during stimulation and an inactive electrical charge
depleted by the battery during inactive periods in which no electrical stimulation is
provided to the patient. The controller is further adapted to determine a time period
25   until an end of service of a power supply associated with the IMD based upon the

active current usage rate and the inactive current usage rates, the active and inactive

electrical charges depleted, and the initial and final electrical charges of the battery.

In still another aspect, the present invention comprises an M D for projecting

5   an EOS and/or an ERI of a battery. The IMD comprises a battery with an initial and a

final (EOS) electrical charge, a stimulation unit providing an electrical stimulation

signal, and a controller. The controller is adapted to determine first and second active

current usage rates for current usage in a first stimulation therapy and a second

stimulation therapy, respectively. The controller is also adapted to determine first and

10   second inactive (i.e., non-stimulating) current usage rates in a first inactive mode and

a second inactive mode, respectively. In addition, the controller is adapted to

determine an active electrical charge depleted by the battery during stimulation and an

inactive electrical charge depleted during inactive periods. The controller also

determines a time period until an EOS and/or an ERI of the battery, based upon the

15   first and second active current usage rates, the first and second inactive current usage

rates, the active and inactive electrical charges depleted, and the initial and final

electrical battery charges.

In another aspect of the present invention, a system is provided for projecting

20   an EOS and/or an ERI of a power supply of an IMD. The system comprises an

external device (i.e., a device outside the body of the patient) for performing remote

communications with the IMD, and the IMD is also capable of communicating with

the external device as well as delivering a stimulation signal to the patient. The IMD

comprises a battery to provide power for delivering the stimulation signal, a

25   communications unit to provide communications between the external device and the

IMD, and a stimulation unit operatively coupled to the battery for providing a stimulation signal. The system also comprises a controller operatively coupled to the stimulation unit and to the battery. The controller comprises a charge depletion circuit for determining both an active charge depletion and an inactive charge

5   depletion of the IMD. The controller further comprises an EOS/ERI circuit for determining a time period until an end of service and/or an elective replacement indication of a power supply associated with the implantable device, based upon the active charge depletion, the inactive charge depletion, and the original and EOS battery charges.

10

In yet another aspect of the present invention, a computer readable program storage device encoded with instructions is provided for projecting an end of service and/or an elective replacement indication of a power supply in an IMD. The computer readable program storage device is encoded with instructions that, when

15   executed by a computer, determine an active charge depletion and an inactive charge depletion of the IMD, and also determines a time period until an end of service and/or an elective replacement indication of a power supply associated with the IMD based upon the determined active charge depletion, the determined inactive charge depletion, and the initial and final battery charges.

20

In another aspect of the present invention, a method is provided for determining an impedance presented by a lead associated with an IMD. In the method, a substantially constant current signal is provided through a first terminal and a second terminal of the lead. A voltage across the first and second terminals is

measured, and an impedance across the first and second terminals is determined based upon the constant current signal provided and the measured voltage.

5   In another aspect of the present invention, an IMD is provided that comprises circuitry for determining an impedance presented by a lead associated with the IMD. The IMD comprises an amplifier circuit for providing a substantially constant current signal through a first terminal and a second terminal of a lead. The IMD further comprises a voltage measurement unit to measure a voltage across the first and second terminals. The implantable device additionally comprises an impedance

10   determination unit to determine an impedance between the first and second terminals based upon the constant current signal and the voltage.

       In another aspect of the present invention, a system is provided for determining an impedance experienced by a lead associated with an IMD. The

15   system comprises an external device communicating with the IMD, and the IMD is in turn adapted to communicate with the external device and to deliver a stimulation signal to a lead coupled to the IMD. The IMD comprises an amplifier circuit for providing a substantially constant current signal through a first terminal and a second terminal of the lead. The IMD also includes a voltage measurement unit to measure a

20   voltage across the first and second terminals, and an impedance determination unit to determine an impedance between the first and second terminals based upon the constant current signal and the measured voltage. The IMD may also include a communications unit for communicating data relating to the impedance determination to the external device.

25

In yet another aspect of the present invention, a computer readable program storage device encoded with instructions is provided for determining an impedance experienced by a lead coupled to an IMD. The computer readable program storage device is encoded with instructions that when executed by a computer, preferably within the IMD, provides a substantially constant current signal through a first terminal and a second terminal of the lead, measures a voltage across the first and second terminals, and determines an impedance across first and second terminals based upon the constant current signal and the voltage.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be understood by reference to the following description taken in conjunction with the accompanying drawings, in which like reference numerals identify like elements, and in which:

5

Figure 1A is a stylized diagram of an implantable medical device suitable for use in the present invention implanted into a patient's body;

Figure 1B is a stylized diagram of another embodiment of an implantable medical device suitable for use in the present invention implanted into a patient's body;

10

Figure 1C illustrates an implantable medical device suitable for use in the present invention, showing the header and electrical connectors for coupling the device to a lead/electrode assembly;

15

Figure 1D shows a lead and electrodes suitable for use in the present invention attached to a vagus nerve of a patient;

20

Figure 2 is a block diagram of an implantable medical device and an external unit that communicates with the implantable medical device, in accordance with one illustrative embodiment of the present invention;

Figure 3 is a stylized diagram of an output current signal provided by the implantable medical device of Figures 1 and 2, provided to illustrate certain stimulation parameters in accordance with one illustrative embodiment of the present invention;

5

Figure 4 is a flowchart representation of a method of providing a warning signal relating to a power supply of the implantable medical device, in accordance with one illustrative embodiment of the present invention;

10   Figure 5 is a flowchart representation of a method of performing a calibration of a charge depletion tabulation, in accordance with one illustrative embodiment of the present invention;

Figure 6 is a more detailed flowchart illustrating a method of performing the

15   charge depletion calculation indicated in Figure 4, in accordance with one illustrative embodiment of the present invention;

Figure 7 is a more detailed flowchart illustrating a method of performing an end-of-service (EOS) and/or an elective replacement indication (ERI) determination,

20   as indicated in Figure 4, in accordance with one illustrative embodiment of the present invention;

Figure 8, is a block diagram of the stimulation unit shown in Figure 2, in accordance with one illustrative embodiment of the present invention;

25

Figure 9 is a block diagram of the impedance measurement unit shown in

Figure 2, in accordance with one illustrative embodiment of the present invention;

Figure 10 is a flowchart of a method of performing an impedance

5   measurement, in accordance with one illustrative embodiment of the present

invention; and

Figure 11 is a flowchart of a method of performing a calibration of an A/D

converter used for impedance measurement, in accordance with one illustrative

10   embodiment of the present invention.

While the invention is susceptible to various modifications and alternative

forms, specific embodiments thereof have been shown by way of example in the

drawings and are herein described in detail. It should be understood, however, that

15   the description herein of specific embodiments is not intended to limit the invention to

the particular forms disclosed, but on the contrary, the intention is to cover all

modifications, equivalents, and alternatives falling within the spirit and scope of the

invention as defined by the appended claims.

20

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Illustrative embodiments of the invention are described herein. In the interest

of clarity, not all features of an actual implementation are described in this

specification. In the development of any such actual embodiment, numerous

25   implementation-specific decisions must be made to achieve the design-specific goals,

which will vary from one implementation to another. It will be appreciated that such a development effort, while possibly complex and time-consuming, would nevertheless be a routine undertaking for persons of ordinary skill in the art having the benefit of this disclosure.

5

Embodiments of the present invention provide methods and apparatus for monitoring and/or estimating the electrical charge depletion of an implantable medical device (IMD). Estimating battery life may be based upon estimated future charge depletion and actual past charge depletion. Embodiments of the present invention

10   provide for an elective replacement indicator (ERI) signal to provide a warning for performing an electrical diagnostic operation upon the EVID. This electrical diagnostic operation may include replacing an electrical component in the IMD, performing additional evaluation(s) of the operation of the EVID, replacing or recharging a power source of the IMD, and the like. A more detailed description of

15   an IMD suitable for use in the present invention is provided in various figures and the accompanying description below.

Generally, IMDs contain power storage devices or battery units to provide power for the operations of the IMD. Embodiments of the present invention

20   determine an estimated usable life remaining in the battery unit based upon determining initial and final battery charges, charge depleted by operations of the IMD, and a future depletion rate. Embodiments of the present invention may be performed in a standalone manner within the IMD itself, or in conjunction with an external device in communication with the IMD. Utilizing embodiments of the

25   present invention, an end of service (EOS) signal or an ERI signal may be provided,

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indicating that the IMD is at or near termination of operations and/or the battery

power has reached a level at which replacement should be considered to avoid

interruption or loss of therapy to the patient.

5   Other embodiments of the present invention provide for determining the lead

impedance. This process involves determining the voltage across a lead associated

with the IMD, based upon the delivery of a constant current signal. The impedance

may be measured on demand or at predetermined periodic intervals to detect

significant changes in impedance across the leads of the EVID. Changes in the

10   impedance may be logged and time-stamped, and saved in a memory in the IMD for

diagnostic considerations. Voltage and current measurements associated with the

IMD may be calibrated using various impedance measurements in order to enhance

the accuracy of lead impedance measurements.

15   Figures 1A-1D illustrate a generator 110 having main body 112 comprising a

case or shell 121 (Figure 1A) with a connector 116 (Figure 1C) for connecting to

leads 122. The generator 110 is implanted in the patient's chest in a pocket or cavity

formed by the implanting surgeon just below the skin (indicated by a dotted line 145),

similar to the implantation procedure for a pacemaker pulse generator. A stimulating

20   nerve electrode assembly 125, preferably comprising an electrode pair, is

conductively connected to the distal end of an insulated electrically conductive lead

assembly 122, which preferably comprises a pair of lead wires (one wire for each

electrode of an electrode pair). Lead assembly 122 is attached at its proximal end to

the connector 116 on case 121. The electrode assembly is surgically coupled to a

25   vagus nerve 127 in the patient's neck. The electrode assembly 125 preferably

comprises a bipolar stimulating electrode pair (Figure ID), such as the electrode pair

described in U.S. Pat. No. 4,573,481 issued Mar. 4, 1986 to Bullara. Persons of skill

in the art will appreciate that many electrode designs could be used in the present

invention. The two electrodes are preferably wrapped about the vagus nerve, and the

5   electrode assembly 125 is preferably secured to the nerve 127 by a spiral anchoring

tether 128 (Figure ID) such as that disclosed in U.S. Pat. No. 4,979,511 issued Dec.

25, 1990 to Reese S. Terry, Jr. and assigned to the same assignee as the instant

application. Lead assembly 122 is secured, while retaining the ability to flex with

movement of the chest and neck, by a suture connection 130 to nearby tissue.

10

In one embodiment, the open helical design of the electrode assembly 125

(described in detail in the above-cited Bullara patent), which is self-sizing and

flexible, minimizes mechanical trauma to the nerve and allows body fluid interchange

with the nerve. The electrode assembly 125 preferably conforms to the shape of the

15   nerve, providing a low stimulation threshold by allowing a large stimulation contact

area with the nerve. Structurally, the electrode assembly 125 comprises two electrode

ribbons (not shown), of a conductive material such as platinum, iridium, platinum-

iridium alloys, and/or oxides of the foregoing. The electrode ribbons are individually

bonded to an inside surface of an elastomeric body portion of the two spiral electrodes

20   125-1 and 125-2 (Figure ID), which may comprise two spiral loops of a three-loop

helical assembly. The lead assembly 122 may comprise two distinct lead wires or a

coaxial cable whose two conductive elements are respectively coupled to one of the

conductive electrode ribbons 125-1 and 125-2. One suitable method of coupling the

lead wires or cable to the electrodes comprises a spacer assembly such as that

25   disclosed in US 5,531,778, although other known coupling techniques may be used.

The elastomeric body portion of each loop is preferably composed of silicone rubber, and the third loop 128 (which typically has no electrode) acts as the anchoring tether 128 for the electrode assembly 125.

5   In certain embodiments of the invention, eye movement sensing electrodes 133 (Figure IB) may be implanted at or near an outer periphery of each eye socket in a suitable location to sense muscle movement or actual eye movement. The electrodes 133 may be electrically connected to leads 134 implanted via a catheter or other suitable means (not shown) and extending along the jawline through the neck 10 and chest tissue to the stimulus generator 110. When included in systems of the present invention, the sensing electrodes 133 may be utilized for detecting rapid eye movement (REM) in a pattern indicative of a disorder to be treated, as described in greater detail below.

15   Alternatively or additionally, EEG sensing electrodes 136 may optionally be implanted in spaced apart relation through the skull, and connected to leads 137 implanted and extending along the scalp and temple and then along the same path and in the same manner as described above for the eye movement electrode leads. Electrodes 133 and 137, or other types of sensors, may be used in some embodiments 20 of the invention to trigger administration of the electrical stimulation therapy to the vagus nerve 127 via electrode assembly 125. Use of such sensed body signals to trigger or initiate stimulation therapy is hereinafter referred to as a feedback loop mode of administration. Other embodiments of the present invention utilize a continuous, periodic or intermittent stimulus signal applied to the vagus nerve (each 25 of which constitutes a form of continual application of the signal) according to a

programmed on/off duty cycle without the use of sensors to trigger therapy delivery. This type of delivery may be referred to as a prophylactic therapy mode. Both prophylactic and feedback loop administration may be combined or delivered by a single IMD according to the present invention. Either or both modes may be

5   appropriate to treat the particular disorder diagnosed in the case of a specific patient under observation.

The pulse generator 110 may be programmed with an external computer 150 using programming software of the type copyrighted by the assignee of the instant

10   application with the Register of Copyrights, Library of Congress, or other suitable software based on the description herein, and a programming wand 155 to facilitate radio frequency (RP) communication between the computer 150 (Figure IA) and the pulse generator 110. The wand 155 and software permit noninvasive communication with the generator 110 after the latter is implanted. The wand 155 is preferably

15   powered by internal batteries, and provided with a "power on" light to indicate sufficient power for communication. Another indicator light may be provided to show that data transmission is occurring between the wand and the generator.

Figure 2 illustrates one embodiment of an IMD 200 (which may comprise

20   pulse generator 110) for performing neurostimulation in accordance with embodiments of the present invention. In one embodiment, the implantable medical device 200 comprises a battery unit 210, a power-source controller 220, a stimulation controller 230, a power regulation unit 240, a stimulation unit 250, an impedance measurement unit 265, a memory unit 280 and a communication unit 260. It will be

25   recognized that one or more of the blocks 210-280 (which may also be referred to as

modules) may comprise hardware, firmware, software, or any combination of the three. The memory unit 280 may be used for storing various program codes, starting data, and the like. The battery unit 210 comprises a power-source battery that may be rechargeable or non-rechargeable. The battery unit 210 provides power for the

5 operation of the IMD 200, including electronic operations and the stimulation function. The battery unit 210, in one embodiment, may be a lithium/thionyl chloride cell or, more preferably, a lithium/carbon monofluoride (Li/CFx) cell. The terminals of the battery unit 210 are preferably electrically connected to an input side of the power-source controller 220 and the power regulation unit 240.

10

The power-source controller 220 preferably comprises circuitry for controlling and monitoring the flow of electrical power to various electronic and stimulation-delivery portions of the IMD 200 (such as the modules 230-265 and 280 illustrated in Figure 2). More particularly, the power-source controller 220 is capable of

15 monitoring the power consumption or charge depletion of the implantable medical device 200 and is capable of generating the ERI and the EOS signals. The power-source controller 220 comprises an active charge-depletion unit 222, an inactive charge-depletion unit 224, and an ERI/EOS calculation unit 226. The active charge-depletion unit 222 is capable of calculating the charge depletion rate of the

20 implantable medical device 200 during active states, and may comprise sub-units to calculate the charge depletion rates of a plurality of active states comprising different charge depletion rates. The active state of the implantable medical device 200 may refer to a period of time during which a stimulation is delivered by the implantable medical device 200 to body tissue of the patient according to a first set of stimulation

25 parameters. Other active states may include states in which other activities are

occurring, such as status checks and/or updates, or stimulation periods according to a second set of stimulation parameters different from the first set of stimulation parameters. The inactive charge-depletion unit 224 is capable of calculating the charge depletion rate of the implantable medical device 200 during inactive states.

5   Inactive states may also comprises various states of inactivity, such as sleep mode, wait modes, and the like. The ERI/EOS calculation unit 226 is capable of performing calculations to generate an ERI signal and/or an EOS signal. One or more of the active charge-depletion unit 222, the inactive charge-depletion unit 224, and/or the ERI/EOS calculation unit 226 may be hardware, software, firmware, and/or any

10   combination thereof.

     The power regulation unit 240 is capable of regulating the power delivered by the battery unit 210 to particular modules of the IMD 200 according to their needs and functions. The power regulation unit 240 may perform a voltage conversion to

15   provide appropriate voltages and/or currents for the operation of the modules. The power regulation unit 240 may comprise hardware, software, firmware, and/or any combination thereof.

     The communication unit 260 is capable of providing transmission and

20   reception of electronic signals to and from an external unit 270. The external unit 270 may be a device that is capable of programming various modules and stimulation parameters of the IMD 200. In one embodiment, the external unit 270 is a computer system that is capable of executing a data-acquisition program. The external unit 270 is preferably controlled by a healthcare provider such as a physician, at a base station

25   in, for example, a doctor's office. The external unit 270 may be a computer,

preferably a handheld computer or PDA, but may alternatively comprise any other

device that is capable of electronic communications and programming. The external

unit 270 may be used to download various parameters and program software into the

IMD 200 for programming the operation of the implantable device. The external unit

5   270 may also receive and upload various status conditions and other data from the

IMD 200. The communication unit 260 may comprise hardware, software, firmware,

and/or any combination thereof. Communications between the external unit 270 and

the communication unit 260 may occur via a wireless or other type of communication,

illustrated generally by line 275 in Figure 2.

10

Stimulation controller 230 defines the stimulation pulses to be delivered to the

nerve tissue according to parameters and waveforms that may be programmed into the

IMD 200 using the external unit 270. The stimulation controller 230 controls the

operation of the stimulation unit 250, which generates the stimulation pulses

15   according to the parameters defined by the controller 230 and in one embodiment

provides these pulses to the connector 116 for delivery to the patient via lead

assembly 122 and electrode assembly 125 (see Figure IA). Various stimulation

signals provided by the implantable medical device 200 may vary widely across a

range of parameters. The Stimulation controller 230 may be hardware, software,

20   firmware, and/or any combination thereof.

Figure 3 illustrates the general nature, in idealized representation, of an output

signal waveform delivered by the output section of a pulse generator 110 (such as

stimulation unit 250 shown in Figure 2) to lead assembly 122 and electrode assembly

25   125 in an embodiment of the present invention. This illustration is presented

principally for the sake of clarifying terminology, including the parameters of signal on-time, off-time, frequency, pulse width, and current. In the treatment of a neuropsychiatric disorder in an exemplary implementation, the stimulation unit 250 of the IMD 200 delivers pulses having a desired output signal current and frequency,

5   with each pulse having a desired output signal pulse width. The pulses are delivered for the duration of the output signal on-time (stimulation period), and are followed by the output signal off-time during which no output signal is delivered (idle period). This periodic stimulation reduces the symptoms of the neuropsychiatric disorder. Stimulation parameters suitable for treatment of a variety of medical conditions can

10   be found in the following patents: US 4,702,254, US 5,025,807, US 4,867,164, and US 6,622,088 (epilepsy); US 5,188,104 and US 5,263,480 (eating disorders); US 5,215,086 (migraine headaches); US 5,231,988 (endocrine disorders); 5,269,303 (dementia); US 5,299,569 and US 6,622,047 (neuropsychiatric disorders); US 5,330,513 and US 6,721,603 (pain); US 5,335,657 (sleep disorders); US 5,540,730

15   (motility disorders); US 5,571,150 (coma); US 5,707,400 (refractory hypertension); US 6,587,719 and US 6,609,025 (obesity); US 6,622,041 (congestive heart failure). Each of the foregoing patents is hereby incorporated by reference herein in its entirety.

20   In one embodiment of the invention, the EVID 200 determines EOS and ERI values by using a known initial battery charge (Q_0) and a predetermined EOS battery charge (QE_0S) indicative of the end of useful battery service, together with the charge actually depleted (Qa) by the IMD (calculated from the current usage rates for idle and stimulation periods $(n$ and $r_s)$, and the length of the respective idle and stimulation

25   periods), to calculate for a desired time point how much useful charge remains on the

battery (Q_r) until the EOS charge is reached, and how long at projected current usage rates the device can operate until EOS or ERI. Once the charge actually depleted by operation of the device (Q_d) is known, the current usage rates are then applied to the remaining useful charge Q_r to determine the time remaining until EOS and/or ERI.

5

The present invention allows EOS and ERI determinations to be made without measurements or calculations of internal battery impedance or other battery parameters. Instead, the device maintains a precise record of the current used during idle and stimulation periods, and subtracts the charge represented by the current used

10   from the total available battery charge to determine the charge remaining on the battery. Because the relative duration of stimulation and idle periods are determined by the stimulation programming parameters of the IMD, a determination of EOS and ERI can be calculated in a straightforward manner based upon the current usage rates associated with the programming parameters.

15

Consistent with the foregoing, Figure 4 provides a flowchart depiction of a method for determining the remaining time to EOS and/or ERI based on known or determined IMD characteristics such as battery charge and current usage rates. In one embodiment, the current usage of the IMD 200 is calibrated during manufacture (step

20   410). Current drawn by the IMD from the battery is defined as electrical charge per unit time. The total charge depleted from the battery as a result of the operations of the IMD may be determined by multiplying each distinct current rate used by the IMD by its respective time used. In one embodiment, as part of the calibration, during manufacturing, a power supply capable of generating known currents and voltages

25   may be used to characterize the power consumption or current depletion of the

implantable medical device 200 during its stimulation and idle modes The power

consumption data thus obtained is preferably stored in a memory of the IMD.

Once the charge usage characteristics of the IMD are known, the battery may

5   be subsequently installed into the implantable medical device 200 for operation and

therafter a record of power consumed by the implantable medical device 200 is

maintained, hi a particular embodiment, the calibration step 410 involves calibration

of current usage for idle periods (ri) and stimulation periods (r_s) of the device. Current

may thus be used as a proxy value for electrical charge depletion, and the calibration

10   step allows a precise determination of the amount of electrical charge used by the

device after implantation. As used herein, the terms "depletion rate," "consumption

rate," and "usage rate" may be used interchangeably and refer to the rate at which

electrical charge is depleted from the battery. However, as noted above, current may

be used as a proxy for electrical charge, and where this is the case, current rates r_i and

15   r_s may also be referred to as "current usage," "current rate," "current consumption,"

"charge depletion," "depletion rate" or similar terms.

As previously noted, the IMD 200 has a number of settings and parameters

(e.g., current, pulse width, frequency, and on-time/off-time) that can be changed to

20   alter the stimulation delivered to the patient. These changes result in different current

usage rates by the IMD 200. hi addition, circuit variations from device to device may

also result in different current usage rates for the same operation. Calculations and

estimations are preferably performed during the manufacturing process in order to

calibrate accurately and precisely the current usage rates of the IMD 200 under a

25   variety of stimulation parameters and operating conditions. A calibration of the

current usage rates and a determination of the charge present on the battery at the time
of implant allow a more accurate assessment of actual and predicted charge depletion
after the IMD 200 is implanted. The initial charge on the battery may include a safety
factor, i.e., the charge may be a "minimum charge" that all batteries are certain to
5   possess, even though many individual batteries may have a significantly greater
charge. Nothing herein precludes a determination of a unique initial charge for each
individual battery. However, it will be recognized that such individual determinations
may not be economically feasible. A more detailed illustration and description of the
step (410) of calibrating current usage and initializing the battery charge for the
10   implantable medical device 200 is provided in Figure 5 and the accompanying
description below.

After calibrating the current usage characteristics of the IMD 200, the IMD
may be implanted and subsequently a charge depletion calculation is performed (step
15   420). This calculation may be performed by the IMD itself, the external unit 270, or
by both, and includes determining the actual electrical charge depleted from the
battery 210 and estimating future current usage (i.e., depletion rates), which are then
used to calculate an elective replacement indication (ERI) and/or an end of service
(EOS) signal (step 430). A more detailed illustration and description of the step 420
20   of calculating the electrical charge depleted is provided in Figure 6 and the
accompanying description below. In step 430 an estimated time until an elective
replacement indication will be generated and/or the estimated time until the end of
service are calculated utilizing the initial battery charge, the actual charge consumed
and the estimated future charge depletion calculated in light of the calibration
25   performed during manufacture. A more detailed description and illustration of the

step 430 of calculating the time to ERI and/or EOS is provided in Figure 7 and the

accompanying description below.

5   Referring now to Figure 5, a flowchart diagram is provided depicting in

greater detail the step 410 (Figure 4) of calibrating and initializing the IMD 200

during manufacturing. In one embodiment, the current rates for the IMD 200 during

stimulation are calibrated (block 510). During manufacturing, several different

combinations of measurements may be calibrated. More specifically, measurements

of charge depletion relating to different types of pulses (i.e., pulses having different

10   stimulation parameters) are calibrated to ensure that current usage measurements for

the IMD are accurate over a wide range of stimulation parameters. In other words,

various pulses having a range of current amplitudes, pulse widths, frequencies, duty

cycles and/or lead impedances into ·which the pulses are delivered are used to

calibrate the measurement of current usage during stimulation to establish a baseline

15   of the measurement of charge depletion for various types of pulses. All operational

variables relating to or affecting the current usage rates of the IMD may be

considered.

More particularly, during manufacture of the IMD 200, several combinations

20   of data points relating to various current rates resulting from various combinations of

pulse parameters are used in one embodiment to generate a linear equation that relates

various pulse parameters to current rate, which may then be used to determine charge

depletion. For example, for a first stimulation, pulses of a certain frequency are

provided and for a second stimulation, the frequency of the pulses used may be

25   doubled. Therefore, the estimated current usage rate for the second stimulation may

be estimated to be approximately double that of the power consumption or charge

depleted due to the first stimulation. As another example, a first stimulation may be

of a first pulse width and a second stimulation may be of a pulse width that is double

that of the width of the first pulse. Therefore, a relationship between the pulse width

5   to the current consumption of the second pulse may be estimated to be approximately

double that of the current usage rate of the first pulse. In one embodiment, a graph

may be generated using the various types of stimulation versus the current

consumption associated with that stimulation.

10   As yet another example, a first stimulation pulse may have a first current

amplitude and a second stimulation may have a current amplitude that is double that

of the first stimulation pulse. Therefore, the current consumption of the second

stimulation pulse may be estimated to be approximately double that of the current

consumption of the first stimulation pulse. The power consumption is directly

15   proportional to the current consumption. Therefore, a relationship of a pulse

parameter to current usage rate may be estimated or measured such that an

interpolation may be performed at a later time based upon the linear relationship

developed during the calibration of the power consumption during stimulation. It

may be appreciated that the relationships of some pulse parameters to current usage

20   rate may not be a simple linear relationship, depending upon such pulse

characteristics as the type of pulse decay (i.e., square wave, exponential decay), for

example. Nevertheless, calibration of current'usage rate for various pulse parameters

may be performed by routine calculation or experiment for persons of skill in the art

having the benefit of the present disclosure.

25

Referring again to Figure 5, current usage during an idle (i.e., non-stimulating) period is calibrated in step 520. From the idle current consumption and the stimulation current consumption calibration, the overall current consumption may be modeled based upon programmed settings. It should be noted that while the invention

5   as shown in the drawings describes a device having two current usage patterns associated with an idle period and a stimulation period, such a two-state embodiment is described solely for clarity, and more complex embodiments are possible involving a third state such as, by way of nonlimiting example, a current usage rate associated ·with electrical sensing of the lead electrodes, which may be defined by a third current

10   rate r_3. Four-state or even higher state embodiments are possible, although where the differences in current usage rates are small, or where a particular current usage rate comprises only a tiny fraction of the overall time of the device, the complexity required to implement and monitor the time such current rates are actually used by the device may render the device impractical. These multi-state embodiments may be

15   implemented if desired, however, and remain within the scope and spirit of the present invention.

Using the calibration of current usage during stimulation periods (step 510) and idle periods (step 520), a calculation may optionally be made to initialize the

20   charge depleted, if any, during manufacturing operations, such as the charge depleted during testing of the device after assembly (block 530). In a preferred embodiment, all of the calibrations are performed with a calibrated current source device, and not a battery, and in this case there is no charge depletion during manufacturing operations. In another embodiment, the amount of charge depleted during manufacturing may

25   small, in which case the initialization procedure may also be omitted. The calibration

and/or initialization steps of Figure 5 allow the IMD 200, via power-source controller 220, to maintain a running tally of how much charge has been depleted from the device. When the battery unit 210 is first inserted into the implantable medical device 200, the charge depleted is generally initialized to zero so that a running tabulation

5   may begin from zero for maintaining a running tally of the charge depleted from the battery over the life of the implantable medical device 200. In one embodiment, the charge depleted tally is incremented throughout the operating life of the device and at any point the running tally may be subtracted from the known initial charge of the battery to determine the remaining charge. In an alternative embodiment, the charge

10   depleted tally could be initialized to the value of the battery initial charge and the tally decremented throughout the device operation and directly used as the remaining charge. In either implementation, information relating to the baseline charge remaining on the battery at the end of manufacturing may be retained to calculate the estimated time to EOS or ERI.

15   Turning now to Figure 6, a flowchart depiction of the step 420 of calculating charge depleted by the device is provided in greater detail. For simplicity, only the two-current state of a single idle period and a single stimulation period is shown. Embodiments having additional current usage rates are included in the present invention. The IMD 200 may determine a current depletion rate r_i for idle periods

20   (block 610). The rate is preferably stored in memory. In one embodiment, the determination is made by the IMD 200 after implantation. In a preferred embodiment, the idle current depletion rate may be a rate determined during manufacturing (i.e., a rate calibrated in step 520) and stored in the memory 280. An idle period is defined as a time period when the implantable medical device 200 is not

25   performing active stimulation, i.e., is not delivering a stimulation pulse to the

electrodes. Various electronic functions, such as tabulation and calculation of numbers or execution of various software algorithms within the IMD 200 may take place during the idle period.

5   As noted, the current rate r_i during idle periods 610 may be predetermined during the manufacturing process (step 520) and may include various considerations, such as the power consumption of the operation of various electronics in the implantable medical device 200, even though no active stimulation may be taking place during that time period. However, since the implantable medical device 200

10   may be occasionally reprogrammed while still implanted inside a patient's body, the number and duration of idle periods may vary according to the duty cycle and frequency of the stimulation pulses. Therefore, the IMD 200 *(e.g.,* via the power source controller 220 in the device) may maintain a running tabulation of the idle periods, and for each idle period a certain amount of charge depleted during the idle

15   period *(i.e.,* off time) is tabulated and stored in memory 280 (step 620).

It will be appreciated that the depleted charge may be obtained in a number of different ways, each within the scope of the present invention. Specifically, the total time of all idle periods since implantation, initialization, or since a previous idle power depletion calculation, may be maintained as a running total idle time in

20   memory, or alternatively a running tally of charge depleted during idle periods may be maintained. While these values are different numerically, they are directly related by simple equations as discussed more fully hereinafter. At an update time, the total idle time may be periodically accessed and multiplied by the idle period current usage rate to determine the total power depleted during idle periods since implantation,

25   initialization, or the previous calculation.

The IMD 200 may also maintain in memory 280 a tabulation of current usage rates (i.e., charge depletion) for a wide range of stimulation settings (step 630). In another embodiment, theoretical charge depletion calculations relating to particular

5   types of stimulation may be provided to the IMD 200. The stimulation parameter settings may then be used by the device to maintain a running tabulation of the charge depleted during stimulation periods using a current usage rate r_s calculated from the pulse width, pulse amplitude, pulse frequency, and other parameters which may impact the current usage rate. This method provides specific current usage rates for a

10   variety of stimulation parameter settings and lead impedances without requiring the storage of current usage rates for all possible stimulation parameter settings and lead impedances.

In one embodiment, the charge depleted may be stored in micro-amp seconds;

15   however, various other measurement units may be utilized. In one embodiment, the IMD 200 itself may be capable of calculating the current usage rate for a particular combination of programmed output settings based upon a known relationship between current usage rates and different combinations of programmed settings. The relationship may then be used to interpolate a particular current usage rate for a

20   particular combination of programmed output settings. However, in order to reduce the computation load on the device, some or all of these calculations, including the interpolation, are preferably performed by an external programmer 270. Therefore, upon programming or performing routine maintenance of the implantable medical device 200, the external unit 270 may perform the calculations to determine the

current usage rate during future stimulation cycles based upon the settings implemented during the programming or maintenance operation.

For example, if the stimulation for a particular patient is set to a particular
5   pulse width, the external device 270 may factor in the calibration data and determine a current usage rate for a particular set of stimulation settings. Therefore, for each stimulation period, the charge that is depleted is tabulated for the stimulation period ("on-time") by multiplying the stimulation time by the current usage rate and a running tabulation is maintained (block 640). For example, if the predetermined
10   current usage rate for each second of stimulation at a particular combination of parameter settings is 100 microamps, and the stimulation is 30 seconds long, a calculation is made by multiplying the 30 second time period for the stimulation, by the 100 microamps to arrive at 3000 micro amp seconds of charge consumed, which is then added to a running charge consumption tally.

15

As illustrated in Figure 6, the sum of the tabulations of the charge depleted for the idle period (off-time or inactive period; step 620) and the charge depleted for the stimulation period (on-time or active period; step 640) are added to arrive at a total charge depleted by the IMD 200 (block 650). It will be appreciated that the sum of
20   idle period and stimulation charge depletion may occur at the conclusion of one or more cycles of idle period and stimulation period, or continuously throughout idle periods and stimulation periods. Occasionally during the operational life of the IMD 200, various stimulation parameters may be changed to provide different types of stimulation. However, utilizing the steps described herein, a running tally (or a
25   periodically updated tally) of the charge depletion is maintained, such that even when

the stimulation settings change, the device maintains a substantially accurate reflection of the actual charge that has been depleted by the IMD 200, and future depletion calculations are based on the depletion rate for the newly programmed settings.

5

The memory 280 may store the results of the charge calculations (step 660). The data stored may include both the current usage rates for idle and stimulation periods of the IMD 200, as well as the total charge depleted. This data may be utilized by the IMD 200 and/or external unit 270 to determine various aspects of the

10   device, including the amount of remaining battery life.

The calculations associated with steps 620, 640 and 650 may be expressed mathematically. In particular, the total charge available from the battery Q_{tot} after it is placed in the IMD 200 may be represented as the difference between an initial battery

15   charge Qo and the EOS battery charge QE_{oss} as expressed in Equation 1.

$$Q_{tot} = Q_0 - Q_{EOS} \qquad \text{Equation 1}$$

The charge depleted by the IMD 200 during idle periods Q_i (step 620) may be expressed as the idle period current usage rate n multiplied by the total duration of all idle periods Δt_i according to equation 2.

20     $$Q_i = r_i \times \Sigma \Delta t_i \qquad \text{Equation 2}$$

Where multiple idle rates are present, the above equation will be solved for each idle current usage rate and the results summed to obtain Q_i. Similarly, the charge depleted during stimulation periods Q_s (step 640) may be expressed as the stimulation period current usage rate r_s multiplied by the total duration of all

25   stimulation periods Δt_s according to equation 3.

$$Q_s = r_s \times \sum \Delta t_s \qquad\qquad \text{Equation 3}$$

Again, where multiple stimulation rates are used the equation will be solved

for each stimulation rate and the results summed. The total charge depleted Q_d is the

sum of Q_i and Q_s, as shown in equation 4.

5
$$Q_d = Q_i + Q_s \qquad\qquad \text{Equation 4.}$$

Finally, the charge remaining until EOS (Q_r) at any arbitrary point in time is

the difference between the total energy or charge available Q_{tot} and the charge actually

depleted from the battery Q_d at that same timepoint, as expressed in equation 5 (step

650).

10
$$Q_r = Q_{tot} - Q_d \qquad\qquad \text{Equation 5}$$

This may be accomplished by counters that record the amount of time the

device uses the idle current usage rate(s) and the stimulation current usage rate(s),

respectively, which are then multiplied by the applicable current usage rate to obtain

the total consumed charge during the idle and stimulation periods.   Alternatively,

15   separate registers may directly maintain a running tally of the charge depleted during

stimulation periods and idle periods, respectively.

Turning now to Figure 7, a more detailed flow chart depicting the calculation

of the time to the end of service (EOS) and/or elective replacement indicator (ERI)

20   signals, as indicated in step 430 of Figure 4, is illustrated.   The IMD 200 is

programmed for delivering to the patient electrical pulses having predetermined

parameters (step 710).   Programming the stimulation settings may be performed

during manufacturing and/or by a healthcare provider when the external unit 270

gains communication access to the IMD 200.   Occasionally, medical personnel may

25   determine that an alteration of one or more of the stimulation parameters is desirable.

Implementation of such changes may easily be accomplished to optimize the therapy

delivered by the IMD.   Alternatively, as part of a routine diagnostic process, a

predetermined change to the stimulation settings may be performed. Additionally, the

IMD 200 may have multiple sets of stimulation parameters stored in memory and may

5   switch between the different stimulation modes represented by those parameters at

preset times or at the occurrence of certain physiological events. When a change in

one or more stimulation parameter settings is implemented (whether by programming

or accessing data from memory), the IMD 200 and/or the external unit 270 may

determine an updated stimulation period current usage rate r_s associated with the new

10   parameter settings, and subsequent updates to the total charge consumed will be based

upon the new stimulation period current usage rate (step 720). The rates may either

be stored in memory or calculated from an equation by interpolation among known

current rates for known parameter settings, as previously described. It is also possible

that changes to the software or firmware of the device could change the idle period

15   depletion rate, in which event a new idle period current usage rate r_i may also be

calculated and reflected in subsequent calculations of total charge depleted (step 720).

Because the duty cycle (on-time to off-time ratio) is also a programmed

parameter, the present invention allows both the idle period current usage rate (r_i) and

20   the stimulation period current usage rate (r_s) to be combined into a single rate for

purposes of projecting future energy or charge depletion and calculating a time to

EOS and/or ERI. This rate represents the total current usage rate (r_t) of the device

(step 725). Following updates to the stimulation and/or idle period current usage rates

r_s and r_i, the updated rates are then used to calculate a new total charge remaining Q_r,

25   by a method substantially as shown in Figure 6 and previously described. Once the

total charge remaining is retrieved from memory, the remaining time to an activation

of an EOS is calculated (step 730) by using the total depletion rate r_t and the total

charge remaining Q_r on the battery until EOS. More particularly, the time remaining

is calculated by dividing the remaining charge by the total depletion rate as shown in

5   Equation 6.

$$t = Q_x / r_t \qquad\qquad \text{Equation 6}$$

At a predetermined time period before the end of service of the battery unit

210 is reached, an ERI signal, which may prompt the healthcare provider and/or the

10   patient to schedule elective replacement of an electronic device, may be asserted to

provide a warning. ERI is typically determined as simply a predetermined time, for

example from 1 week to 1 year, more typically 6 months, earlier than EOS. In an

alternative embodiment, the ERI signal may be defined as a particular charge level

remaining (QERI) above the EOS charge, $Q_{EO}s$. In this embodiment, the time period

15   remaining until the ERI signal could be calculated by dividing QE_{OS} by the total

depletion rate r_t and subtracting the resulting time period from the time to EOS as

calculated in equation 6.

The time to EOS provides a warning to the healthcare provider and/or patient

20   that the energy or charge supply will be depleted very shortly. Therefore, the time to

EOS is reported to the implantable medical device 200 and/or to the external device

270 (block 740). The ERI is also reported to the implantable medical device 200

and/or to the external device 270, which is then brought to the attention of the patient

and/or a medical professional.

25

In addition to battery life, for diagnostic purposes the impedance of the various leads that deliver stimulation provided by the IMD 200 is also of interest. Lead impedance measurements and known output current signal characteristics may be used to calculate consumed stimulation charge. Sudden changes in lead impedance

5   may indicate any of a number of changes in the operation of the implantable medical device 200.   Changes in impedance may indicate that the leads delivering the stimulation have moved or have been damaged, or that the patient's body where the stimulation was delivered may have changed in some way.

10   Turning now to Figure 8, a block diagram is provided depicting in further detail an embodiment of the stimulation unit 250 of Figure 2. The stimulation unit · 250 of the IMD 200 comprises an op amp unit 820, which may comprise one or more operational amplifiers that are capable of delivering a controlled current signal for stimulation.   In one embodiment, the controlled current is a constant current or a

15   substantially constant current.   The stimulation unit 250 may also comprise an amplifier control circuitry unit 810 that may contain circuitry and/or programmable logic to control the operation of the op amps 820. Additionally, the stimulation unit 250 may be coupled to leads 122, which may comprise a pair of signal wires capable of delivering an electrical signal to an electrode pair 125-1 and 125-2 (Figure ID)

20   each coupled to a distal end of one of the leads 122. The leads 122 (and the electrodes 125-1 and 125-2) are capable of providing a complete circuit between the implantable medical device 200 and the region of the body/tissue to which the electrodes are attached, which may be approximated as an equivalent impedance. Each lead 122 may comprise a single strand wire or, more preferably, a multi-strand

25   wire braided or otherwise coupled together as a single functional wire. Each of the

two lead wires 122 in this embodiment is provided with a separate socket and connector 116, as shown in Figure 1C. In another embodiment, two leads 122 may be combined into a single coaxial cable (as shown in Figures 1A and 1D), with a single socket providing both coaxial connectors 116.

5

Embodiments of the present invention provide for utilizing the delivery of a constant current signal for delivery of stimulation, and measurement of the impedance experienced by the leads 122. In a preferred embodiment, the controlled or constant current signal provided by the stimulation unit 250 is independent of the impedance

10 experienced across the leads 122. For example, even if the impedance experienced across the leads 122 changes, the op amp 820, in conjunction with the amplifier control circuitry 810, adjusts to deliver a controlled or constant current despite the change in the impedance experienced across the leads 122.

15 Since a controlled, constant current is delivered despite variations in the impedance across the leads 122, the voltage across the lead terminals provide an indication of the lead impedance. For example, if the nerve tissue to which the leads 122 are connected has an impedance of 1000 ohms, a particular stimulation may call for a one milliamp constant current signal. In this case, even if a 5000 ohms

20 impedance is experienced across the leads 122, the stimulation unit 250 will still provide a one milliamp current. Hence, the power may vary but the current remains constant. In other words, the op amp 820 will stabilize itself utilizing various circuitry, including the amplifier control circuitry 810, to provide a constant current signal even if the impedance experienced by the leads 122 varies during the period the

25 signal is provided. Therefore, using Ohm's Law, $V = IR$, a measurement of the

voltage across the leads 122 will provide an indication of the actual impedance experienced by the leads 122.

Turning now to Figure 9, a block diagram depiction of one embodiment of the
5   impedance measurement unit 265 from Figure 2 is provided. In one embodiment, the impedance measurement unit 265 comprises a voltage measurement unit 910, an A/D converter (analog to digital converter) 920 and an impedance calculation unit 930. The voltage measurement unit 910 is capable of measuring or determining the voltage differential between the terminals of the leads 122. The signal from the voltage
10   measurement unit 910 is generally an analog signal, which may be sent to the A/D converter 920. The A/D converter 920, which preferably has been calibrated prior to the operation of the IMD 200, will convert the analog voltage measurement signal to a digital signal. In alternative embodiments of the present invention the impedance measurement unit 265 may be implemented without the use of the A/D converter 920
15   and still remain within the scope of the present invention.

Although certain embodiments may be implemented without it, the A/D converter 920 may be beneficial for enhancing the resolution of the voltage signal, thereby providing for enhanced analysis of the voltage across the leads 122. Based
20   upon the voltage across the leads 122, and the constant current signal provided by the stimulation unit 250, the impedance calculation unit 930 calculates the impedance by dividing the voltage across the lead terminals 122 by the current delivered by the stimulation unit 250. The impedance calculation unit 930 may be a hardware unit, a software unit, a firmware unit, or any combination thereof, which may be located in
25   various portions of the IMD 200, including in the impedance measurement unit 265,

in the stimulation controller 230, in the power source controller 220, or in any other portion of the IMD 200.

In an alternative embodiment, the calculation described as being performed by
5   the impedance calculation unit 930 may alternatively be performed by the external unit 270, which may receive the signal relating to the constant current stimulation signal and the measured voltage signal. One of the advantages of utilizing the embodiments provided by the present invention is that substantially any size of a constant or controlled current stimulus signal may be used to perform the impedance
10 measurement, thereby conserving battery power of the implantable medical device 200. Accordingly, the smallest stimulation signal that may reliably be provided by the stimulation unit 250 may be used to perform the impedance measurement. Thus, the impedance measurement may be made without imposing a significant charge depletion burden on the battery. Additionally, the impedance of the leads 122
15 themselves is also accounted for when analyzing the impedance. Furthermore, the A/D converter 920 may be calibrated prior to the operation of the implantable medical device 200, for example, during the manufacturing process.

Turning again to Figures IA- ID, the leads 122 are shown connected to tissue
20 (e.g., nerve tissue 127) in a patient's body and to the IMD 200. The implantable medical device 200 may comprise a main body 112 (Figure IA) in which the electronics described in Figure 2 are enclosed. Coupled to the main body 112 is a header 114 (Figure IA) designed with terminal connectors 116 (Figure 1C) for connecting to leads 122. The main body 112 may comprise a titanium case 121 and
25 the header 114 may comprise a biocompatible polymer such as polyurethane or

acrylic. The leads 122 projecting from the header 114 may be attached to the tissue

utilizing a variety of methods for attaching the leads 122 to tissue. A first end of the

leads 122 is coupled to connector(s) 116 on the header 114, and a distal end is

coupled to the tissue by electrodes 125-1 and 125-2, which together provide a cathode

5   and an anode (Figure ID). Therefore, the current flow may take place from one

electrode 125-1 to a second electrode 125-2 via the tissue, thereby delivering the

stimulation.

The system illustrated in Figures 1A-ID may be viewed as an electrical circuit

10   that includes a current or voltage source *(i.e.,* the battery 210 of the IMD 200) being

connected to an impedance *(i.e.,* the equivalent impedance of the tissue) via a pair of

wires *(i.e.,* the leads 122). The total impedance connected to the IMD 200 includes

the impedance of the lead wires 122 as well as the impedance across the terminals 116

of the leads 122 to the tissue. One of the biggest components of the impedance

15   experienced by terminals 116 on the header 114, to which the leads 122 are

connected, is the impedance of the tissue. Therefore, if a break in any one portion of

the lead wires 122 occurs (such as a break in one or more strands of a multistrand

wire), the impedance may rise significantly, which may provide an indication that a

break in the lead wire 122 has occurred.

20

Turning now to Figure 10, a flowchart depicting steps for determining the

impedance experienced by the leads 122 of the IMD 200 is provided. As shown in

step 1010, stimulation is delivered by the IMD 200 to the tissue of the patient by one

of a number of available stimulation delivery modes, such as a constant current signal

25   pulse (step 1010). To conserve battery power, impedance may be determined using a

small magnitude and/or short duration pulse. The resultant voltage induced across the leads 122 is measured (block 1020) upon delivery of the stimulation signal. Voltage measurement may be performed by a voltage measurement unit 910 (Figure 9) during delivery of the stimulation current signal. The IMD 200 adjusts the time at which the

5   voltage is measured such that it occurs while the stimulation current signal is being delivered.

An analog-to-digital *(A/D)* conversion is preferably performed on the voltage signal (block 1030). Although, embodiments of the present invention may be

10   performed without utilizing an A/D converter 920, in a preferred embodiment an A/D converter 920 (Figure 9) is used to provide precise resolution of the voltage signal. The A/D converter 920 is preferably calibrated prior to the conversion of the voltage signal from analog to digital. Finally, the impedance is calculated utilizing the amplitude of the current delivered for stimulation and the corresponding voltage

15   measurement, as shown in step 1040. The voltage resulting from the current signal delivered as stimulation is divided by the value of the current to arrive at the total impedance across the terminals 116 of the header 114 (Figures IA- ID). In one embodiment, the predetermined impedance of the lead 122 itself may be subtracted to arrive at the impedance across the lead terminals 116, which corresponds to the

20   impedance of the tissue 1030. Various operational adjustments to the operation of the IMD 200 may be made based upon the determination of the impedance across the terminals 116.

Figure 11 provides a flowchart depicting the steps for performing the

25   calibration of the A/D converter 920 (Figure 9). In a preferred embodiment, the

calibration of the A/D converter 920 is performed prior to implanting the IMD 200 in

the body of the patient, more preferably during the manufacturing process of the IMD

200. Referring to Figure 11, a predetermined, known impedance is provided for the

calibration of the A/D converter 920, as depicted in step 1110. The known impedance

5   is electrically connected across the two distal ends of leads 122 (which may or may

not include electrode assembly 125), and the other ends of the lead wires 122 are

connected to the terminals 116 of header 114 (step 1220). With the leads 122

connected between the IMD 200 and the known impedance, a constant current test

signal is driven through the lead 122, through the known impedance, and back to the

10   IMD 200 (step 1130).

The constant current test signal may comprise a series of individual constant

current signals that may vary in duration of current amplitude from one signal to

another in the series of test signals, provided that each individual test pulse comprises

15   a constant current. During the delivery of each constant current test pulse to the

known impedance, a corresponding voltage resulting from the driving of the constant

current is measured across the terminals 116 of the IMD 200 (step 1240). This

measurement of voltage at the terminals 116 allows a comparison to a theoretical

indication of what the measurement should be by calculation from the known current

20   being driven, and the known impedance across the leads 122. This theoretical

voltage calculation value is then used with the actual voltage measured across the

terminals 116 to calibrate the A/D converter 920 (block 1150). Calibration of the A/D

converter 920 should provide improved accuracy for measurements subsequently

processed by the A/D converter 920. In another embodiment, the calibration process

25   may be performed using multiple known impedances and corresponding resulting

multiple measured voltages. Such a calibration over a range of impedances may provide further improved accuracy.

5   Utilizing embodiments of the present invention, a more accurate assessment of the status of the battery and the impedance experienced by the leads 122 may be assessed, thereby providing better warnings to the user and/or to a healthcare provider assessing the operations of the IMD 200. Various end of service signals (EOS) and/or elective replacement indication (ERI) signals may be provided to indicate the status of the operation of the IMD 200. Additionally, the impedance experienced by the leads

10   122 of the IMD 200 may be analyzed to assess the integrity of the leads 122 or any drastic changes in the tissue to which the stimulation signal is provided.

         The particular embodiments disclosed above are illustrative only, as the invention may be modified and practiced in different but equivalent manners apparent

15   to those skilled in the art having the benefit of the teachings herein. Furthermore, no limitations are intended to the details of construction or design herein shown, other than as described in the claims below. The particular embodiments disclosed above may be altered or modified and all such variations are considered within the scope and spirit of the invention. Accordingly, the protection sought herein is as set forth in the

20   claims below.

CLAIMS

WHAT IS CLAIMED:

1.   A method for determining an impedance associated with a lead

5   assembly in an implantable medical device, said lead assembly comprising a first

terminal and a second terminal, said method comprising:

        providing a controlled current signal through said first terminal and said

        second terminal;

        measuring a voltage across said first and second terminals; and

10   determining the impedance across said first and second terminals based upon

        said constant current signal and said voltage.

2.   The method of claim 1, wherein said controlled current is a

substantially constant current.

15

3.   The method of claim 2, wherein providing a substantially constant

current signal comprises providing a current signal that is independent of the

impedance across said lead terminals.

20   4.   The method of claim 2, wherein measuring said voltage across said

first and second terminals comprises measuring said voltage that results from said

constant current signal.

5.   The method of claim 2, wherein determining an impedance across said

25   first and second terminals of said lead assembly further comprises dividing said

measured voltage by the magnitude of said constant current signal.

6.   The method of claim 2, wherein determining an impedance across said

first and second terminals of said lead assembly comprises dividing said measured

voltage by the magnitude of said constant current signal, and then subtracting an

5   impedance associated with said first and second terminals.

7.   The method of claim 2, wherein measuring said voltage across said

first and second terminals comprises converting said voltage signal from analog to

digital using an analog-to-digital converter.

10

8.   The method of claim 2, further comprising calibrating said analog-to-

digital converter using a known impedance and driving a known current signal across

said known impedance to calibrate said analog-to-digital converter based upon a

resultant theoretical voltage.

15

9.   An implantable medical device, comprising:

an amplifier circuit for providing a substantially constant current signal

        through a first terminal and a second terminal of a lead assembly;

a voltage measurement unit to measure a voltage across said first and second

20   terminals; and

an impedance measurement unit to determine an impedance between said first

        and second terminals based upon said constant current signal and said

        measured voltage.

10. The implantable medical device of claim 9, wherein said implantable medical device is a vagus nerve stimulator device.

11. The implantable medical device of claim 9, further comprising an

5 analog-to-digital converter to convert said voltage from an analog signal to a digital signal for measurement.

12. The implantable medical device of claim 9, wherein said voltage measurement unit is adapted to measure the voltage resulting from an application of

10 said constant current signal across said first and second terminals of said lead assembly.

13. The implantable medical device of claim 9, wherein said impedance measurement unit is adapted to divide the magnitude of said voltage by the magnitude

15 of said constant current signal.

14. The implantable medical device of claim 9, wherein said impedance measurement unit is adapted to divide the magnitude of said voltage by the magnitude of said constant current signal and subtract an impedance value associated with said

20 first and second terminals.

15. A system for measuring the impedance of a lead assembly in an implantable medical device, said lead assembly comprising first and second terminals, comprising:

an external device for performing remote communications with an implantable

medical device;

an implantable medical device adapted to communicate with said external

device and to deliver a stimulation signal to a patient via a lead assembly, said

5   implantable device comprising:

an amplifier circuit for providing a substantially constant current signal

through said first terminal and said second terminal of said lead assembly;

a voltage measurement unit to measure a voltage across said first and

second terminals;

10   an impedance measurement unit to determine an impedance between

said first and second terminals based upon said constant current signal and

said voltage; and

a communications unit for providing said impedance determination to

said external device.

15

16.   The system of claim 15, wherein said implantable device is a vagus

nerve stimulator.

17.   The system of claim 15, wherein said communications unit is capable

20   of providing wireless communications with said external device.

18.   The system of claim 17, wherein said external device comprises a

computer system capable of executing at least one of a communication program and a

data acquisition program.

25

19. The system of claim 18, wherein said external device is capable of transmitting software code to said implantable device, and said implantable medical device is capable of receiving and executing said code.

5   20. The system of claim 15, wherein said implantable medical device further comprises an analog-to-digital converter to convert said voltage from an analog signal to a digital signal for measurement.

21. The system of claim 15, wherein said voltage measurement unit is 10 adapted to measure the voltage that resulting from an application of said constant current signal across said first and second terminals of said lead assembly.

22. The system of claim 15, wherein said impedance measurement unit is adapted to divide said voltage by the magnitude of said constant current signal.

15

23. The system of claim 15, wherein said impedance measurement unit is adapted to divide said voltage by the magnitude of said constant current signal, and subtract an impedance value associated with said first and second terminals.

20   24. An apparatus for determining an impedance associated with a lead medical assembly of an implantable medical device, comprising:

means for providing a substantially constant current signal through a first

terminal and a second terminal of said lead assembly; and

means for measuring a voltage across said first and second terminals; and

means for determining an impedance across said first and second terminals based upon said constant current signal and said measured voltage.

25.   A computer readable program storage device encoded with instructions that, when executed by a computer, performs a method for determining an impedance associated with a lead assembly having first and second terminals and comprising a component of an implantable medical device, comprising:

providing a substantially constant current signal through said first terminal and said second terminal of said lead assembly;

measuring a voltage across said first and second terminals while said constant current is provided; and

determining an impedance across said first and second terminals based upon said constant current signal and said measured voltage.

26.   The computer readable program storage device of claim 25, wherein providing a constant current signal comprises providing a current signal that is independent of the impedance across said first and second terminals of said lead assembly.

27.   The computer readable program storage device of claim 25, wherein measuring said voltage across said first and second terminals comprises measuring said voltage resulting from said constant current signal.

28. The computer readable program storage device of claim 25, wherein determining an impedance across said first and second terminals comprises dividing said measured voltage by the magnitude of said constant current signal.

5   29. The computer readable program storage device of claim 25, wherein said lead assembly further comprises first and second lead wires coupled to tissue of a patient, and wherein said step of determining an impedance across said first and second terminals comprises dividing the magnitude of said voltage by the magnitude of said constant current signal, and subtracting an impedance associated with said first

10   and second lead wires.

30. The computer readable program storage device of claim 25, wherein measuring said voltage across said first and second terminals further comprises converting said voltage signal from analog to digital using an analog-to-digital

15   converter.

31. The computer readable program storage device of claim 25, further comprising calibrating said analog-to-digital converter using a known impedance and driving a known current signal across said known impedance to calibrate said analog-

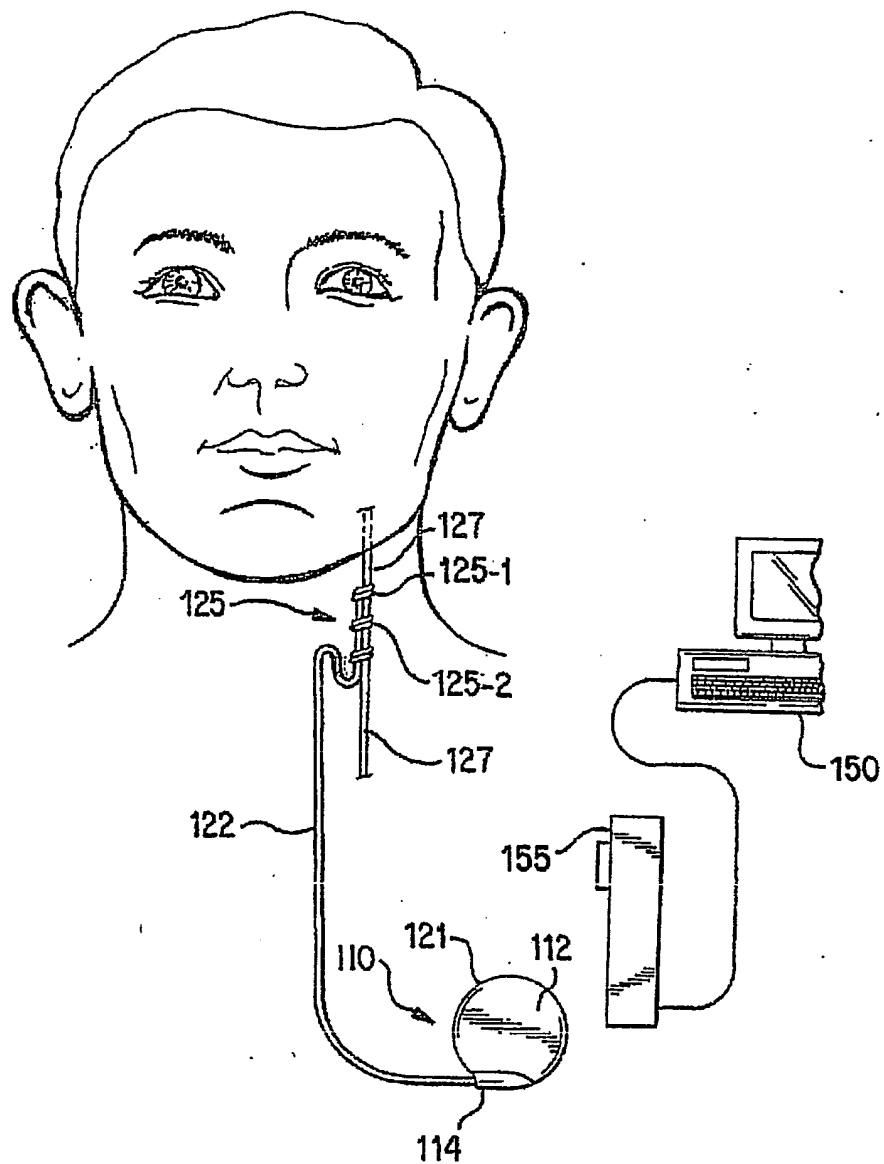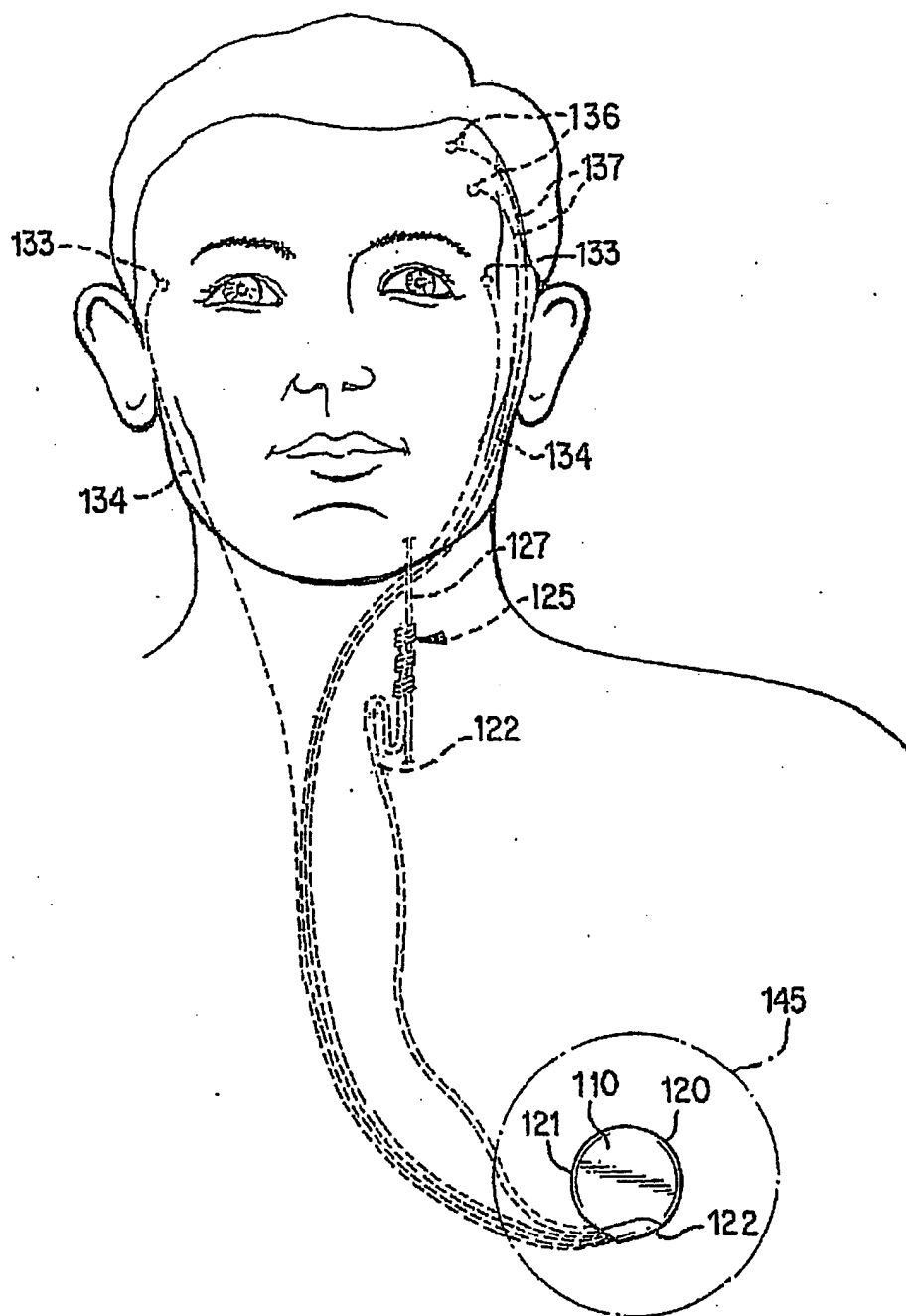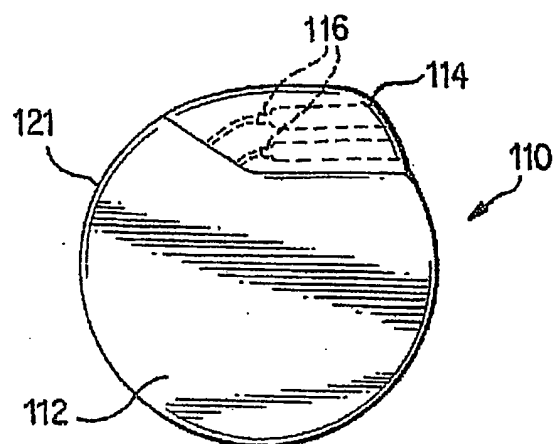20   to-digital converter based upon a resultant theoretical voltage.
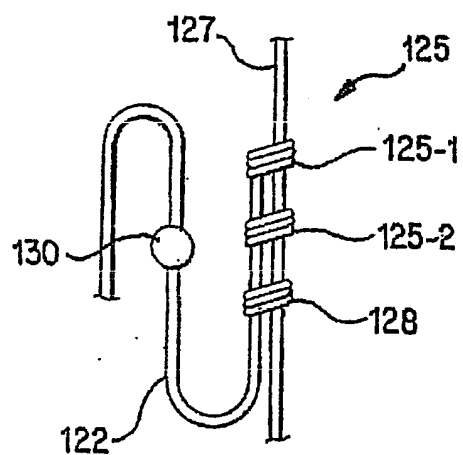
FIG. 1A

FIG. 1B

FIG. 1C

FIG. 1D

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FIGURE 2

Output Signal Off Time

Output Signal On Time

Output Signal Current

Output Signal Pulse Width

$1/f$ f = Output Signal Frequency

FIGURE 3

Calibrate and Initialize Charge Depletion During Manufacturing — 410

Calculate Charge Depletion and Estimate Future Charge Depletion — 420

Calculate Time to End of Service (EOS) and/or Elective Replacement Indication (ERI) — 430

FIGURE 4

7 / 13

Calibrate Measurement of Charge Depletion for a Range of Stimulation Pulse Parameters

Calibrate Measurement of Idle Consumption

Initialize Charge Depleted

510

520

530

FIGURE 5

120

630 — Determine depletion rate for stimulation settings

640 — For each stimulation period, add charge consumed during the period (on-time) to obtain Q_s

610 — Determine depletion rate for idle period(s)

620 — For each idle period, add charge consumed by idle period (off-time) to obtain Q_i

650 — Accumulate all of the energy depleted to arrive at total charge depleted, Q_d, and charge remaining Q_r

660 — Store total charge depletion calculation result in stimulator

FIGURE 6

FIGURE 7

Program Stimulation Parameters

Determine Updated Stimulation and/or Idle Charge Depletion Rate

Calculate Total Depletion Rate, r_t

Determine Remaining Time to EOS and/or ERI using Q_r (Figure 6) and r_t

Store EOS and ERI in Stimulator and/or Transmit to External Device

710

720

725

730

740

430

STIMULATION UNIT

250

Amplifier Control Circuitry

810

Op Amp(s)

820

Constant Current for Stimulation

122

122

FIGURE 8

IMPEDANCE MEASUREMENT UNIT

Voltage Measurement Unit

910

A/D Converter

920

Impedance Calculation Unit

930

265

FIGURE 9

Deliver Stimulation — 1010

Measure Voltage — 1020

Perform A/D conversion on the voltage signal — 1030

Calculate impedance based upon known current and measured voltage — 1040

FIGURE 10

Provide Known Impedance — 1110

Connect impedance to leads, which is conneced to the implantable device — 1120

Drive Constant Current — 1130

Measure Resultant Voltage — 1140

Calibrate A/D based upon expected voltage value — 1150

FIGURE 11